

MULTICENTRE RANDOMISED TRIAL OF TENSION-FREE VAGINAL TAPE AND COLPOSUSPENSION FOR PRIMARY URODYNAMIC STRESS INCONTINENCE: FIVE YEAR FOLLOW UP.

Hypothesis / aims of study

The aim of this study was to compare tension-free vaginal tape (TVT) with colposuspension for the treatment of primary urodynamic stress incontinence. Previously reported results from this trial, which was initially set up in 1997, showed TVT to be as effective as colposuspension for the treatment of urodynamic stress incontinence up to two years with fewer post operative complications and shorter hospital stay and recovery. (1,2) The five year follow up study aimed to assess the comparative long term success of the two procedures and to provide further data on uterovaginal prolapse, tape erosion and other complications.

Study design, materials and methods

The trial was conducted in gynaecology and urology departments in 14 centres in the UK and Ireland. Women with urodynamic stress incontinence were randomised to TVT or colposuspension. None had detrusor overactivity, major voiding problems, prolapse requiring treatment or previous surgery for incontinence or prolapse at the time of recruitment.

Assessment performed prior to treatment and at five years post operatively included the following: symptom review, clinical examination, Bristol female lower urinary tract symptoms (BFLUTS) questionnaire, SF-36 health survey and 1 hour pad test.

The primary outcome measure was cure of stress incontinence based on a negative 1-hour pad test. Secondary outcome measures included subjective cure measured by the BFLUTS questionnaire, and the development of voiding problems, urgency and vaginal prolapse.

The sample size calculation was performed assuming a 90% cure for colposuspension and that a 10% difference in cure between procedures would be clinically important. 197 patients would be required in each arm to detect this difference with 80% power.

Results

344 women with urodynamic stress incontinence were randomly assigned to groups: 175 to TVT and 169 to colposuspension. 28 women withdrew before surgery, 5 in the TVT group and 23 in the colposuspension group. 98 of those who had TVT and 79 of those having colposuspension returned for 5 year follow up; 72 in the TVT group and 49 in the colposuspension group with full subjective and objective data. The reasons for missing data at 5 years were: loss due to investigator withdrawal (21 TVT and 17 colposuspension), loss to follow up (40 and 39) and patient withdrawal (11 and 11). There were no differences in baseline characteristics between the two groups who attended. The baseline characteristics of women who underwent surgery but failed to attend for 5 year follow up did not differ from those continuing in the trial.

Primary outcome measure:

A negative 1 hour pad test was recorded in 58/72 (81%) of the TVT group and 44/49 (90%) of the colposuspension group. ($p=0.21$, Fisher's exact test). Sensitivity analysis was performed to exploring the effect of different assumptions about patients lost to follow up. No differences in cure were shown between the two procedures, for any of the assumptions.

Secondary outcomes:

- **Symptoms** Significant reductions in the reporting of symptoms of frequency, urgency, urge, stress and unexplained incontinence were seen in both groups five years after surgery. De novo urgency and urge incontinence occurred in 2 (2%) and 1 (1%) of the TVT group respectively and 4 (5%) and 3 (4%) of the colposuspension group. 38/98 (39%) in the TVT group and 36/79 (46%) in the colposuspension reported no leakage under any circumstances 5 years after surgery. The number reporting cure of stress leakage was 62/98 (63%) and 55/79 (70%) respectively. Incontinence during intercourse and disruption of sex life by urinary symptoms in general were less commonly reported following both procedures. Overall, 91% of the TVT patients and 90% of the colposuspension patients regarded themselves as satisfied or very satisfied with the results of their surgery at 5 years.
- **Quality of life** No differences were seen between the two groups in any of the health dimensions measured by the SF-36 health status questionnaire at 5 years
- **Prolapse** Significant reduction in the finding of cystocele was found in both groups at 5 years. Both enterocele or vault/cervical prolapse and rectocele were found more commonly in the colposuspension group 5 years after surgery.

Complications:

Four in the TVT group and five in the colposuspension group underwent re-operation for stress incontinence during the follow up period. 3/170 (1.8%) women in the TVT arm and 11/146 (7.5%) in the colposuspension group had surgery for prolapse in this time ($p=0.025$, Fisher's exact test). Tape related complications were seen in six patients. In the first year, one tape was divided for obstructed voiding; there was one suprapubic extrusion and one vaginal erosion. Two further vaginal erosions occurred at 5 years. Intravesical tape was removed by cystotomy at 5 years, in a patient complaining of overactive bladder symptoms. This patient was noted to have a bladder abrasion on cystoscopy at the time of TVT; no intravesical tape was identified and she was treated with antibiotics and indwelling catheterisation. There were no reported suture related complications in the colposuspension group.

Interpretation of results

To date there have been few randomised trials of surgery for stress incontinence with long-term follow up. Although this is one of the largest trials of surgery for stress incontinence, its impact is somewhat limited by the high number of post randomisation drop outs, both before surgery in the colposuspension group, and after surgery in both groups. The conclusions about cure that can be drawn from this trial are heavily dependent on the handling of missing data and the assumptions made about those who withdrew. Although we have not demonstrated a difference between the procedures for cure of stress incontinence, we cannot be certain that a difference does not exist from this data.

Of patients who attended for follow up, subjective and objective cure rates are maintained at the same level as previously reported at 6 months and 2 years. This is compatible with published evidence concerning long term cure rates for colposuspension and 7 year results for TVT.(3)

Our data support the findings of other authors of a high incidence of posterior vaginal wall and vault prolapse post colposuspension. This has not been noted in the TVT group and it is likely that colposuspension is causative.

One of the major concerns about synthetic sling materials is their potential to erode into the urinary tract and vagina. It has been suggested that these are the result of failure of vaginal skin healing rather than true erosion. There were two true vaginal erosions (only one of which was symptomatic) in the 72 patients examined at 5 years. Although these patients suffered only minimal morbidity, it is important to be aware that synthetic sling materials have the potential to erode many years after implantation. The patient who was found to have intravesical tape may have had an unrecognised perforation at the time of operation.

Concluding message

The TVT appears to be as effective as colposuspension for the treatment of stress incontinence at 5 years. The effect of both procedures on cure of incontinence and improvement in quality of life and sexual health is maintained in the long term. Vault and posterior vaginal wall prolapse are seen more commonly following colposuspension. Whilst many tape related complications may be missed operative injury, tape erosion may occur several years after surgery.

(1) British Medical Journal, 2002. **325**(7355): p. 67-70

(2) Am J Obstet Gynecol, 2004. **190**(2): p. 324-31

(3) Obstet Gynecol, 2004. **104**(6): p. 1259-62

FUNDING: KW was supported by a grant from Ethicon Ltd who also provided materials and additional support to collaborating centres

DISCLOSURES: KW was supported by a grant from Ethicon Ltd. PH and KW have been reimbursed by Ethicon Ltd for conferences expenses where this, and related work has been presented; neither have any financial interest in this or any other company.

CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.

HUMAN SUBJECTS: This study was approved by the UK Multicentre research ethics committee (Ref: MREC/97/03/18) and followed the Declaration of Helsinki Informed consent was obtained from the patients.